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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,977	02/26/1999	JAMES M. WILSON	GNVPN.019BUS	1765

7590 10/30/2002

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EXAMINER
SHUKLA, RAM R

ART UNIT	PAPER NUMBER
1632	29

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/242,977	Applicant(s) WILSON ET AL.	
	Examiner Ram R. Shukla	Art Unit 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *19-24,26-28 and 30-35*.

   Claim(s) withdrawn from consideration: *None*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

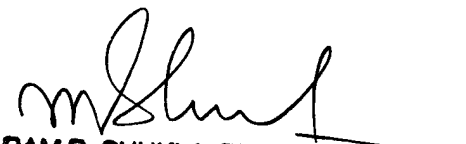
RAM R. SHUKLA, PH.D
PATENT EXAMINER

Ram R. Shukla
Examiner
Art Unit: 1632

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments have been fully considered, however they are not persuasive. Regarding the 112 first paragraph wirtten description rejection, applicants have argued that the specification describes on page 35, lines 1-5 support for the limitation. However, as noted in the previous office action, the limitation of "wherein the recombinant AAV is at least as free of the contaminating adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation" would encompass "equal to" or "more" pure recombinant AAV composition compared to the preparation of recombinant AAV obtained after four rounds of cesium chloride centrifugation. Cited section of the specification describes " lacking detectable levels of adenovirus", however this can not provide written description support since detectable level may change based on the assay used. Even if one had to accept that there was description for "equal to", there is no support for "more pure". Applicants arguments that inventors for the first time described that contamination with adenoviral helper virus induces immune response is not relevant here since the issue is of written support for a term.

Applicants respone regarding double patenting is acknowledged.

Regarding the 103, rejection, applciants' arguments are not persuasive. It is not clear as to what point was made by referring to a quotation from Fisher et al, page 521, since the quotation says that by the third round of centrifugation, all detectable helper virus is removed. Regarding the issue of contamination levels, the arugments made by the applicants are not relevant since the number of adenoviral helper virus concentration is not recited in the claims. Applicants have reiterated that none of the cited documents recognize the importance of removing contaminating helper adenovirus from rAAV preparations. However, this argument is not persuasive and as noted in the previous office action, in fact Podaskoff realized this problem. It is not clear as to how eliminating function of contaminating adenoiral helper is different from eliminating contaminating helper virus itself, since for elimnating function one has to remove the helper virus. Therefore, the 103 rejection is maintained for reasons of record set forth in the previous office actions of 7-22-02 and 11-23-01. .



RAM R. SHUKLA, PH.D
PATENT EXAMINER